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Submitter:	St. Jude Medical 1350 Energy Lane, Suite 110 St. Paul, MN 55108 Phone: 651-523-6900 Fax: 651-523-6990
Contact:	Karen J. McKelvey Regulatory Manager II
Date Prepared	May 19, 2009
Trade Name:	EnSite System™ (Model EE3000) a) EnSite Array™ (Model EC1000) b) EnSite NavX™ Surface Electrode Kit (Model EN0010)
Common Name	Electrophysiology mapping system with console and catheter
Classification Name:	Programmable diagnostic computer (21 CFR 870.1425)
Predicate Device:	**EnSite System K070902**
Device Description:	The EnSite System is a computerized storage and display system for use in electrophysiology studies of the human heart. The system consists of a console workstation, patient interface unit, and an electrophysiology mapping catheter or surface electrode kit. Unlike currently available electrode recording catheters, the EnSite Array does not require direct contact with the endocardium for the detection of intracardiac electrograms. The EnSite System is a system that facilitates mapping and treatment of arrhythmias. When used with the EnSite catheter, the system is useful for treating patients with complex, non-sustained, or poorly tolerated arrhythmias that are difficult, if not impossible, to map with current mapping techniques. By visualizing the global activation pattern seen on the color-coded isopotential maps in the EnSite System, in conjunction with the reconstructed electrograms, the electrophysiologist can identify the arrhythmia source and can navigate to the defined area for therapy. When used with NavX patches, the system is useful in treating patients with simpler arrhythmias by providing non-fluoroscopic navigation and visualization of conventional EP catheters

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Intended Use:

The EnSite System is a suggested diagnostic tool in patients for whom electrophysiology studies are indicated.

- When used with the EnSite Catheter, the EnSite System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

OR

- When used with the EnSite NavX Surface Electrode Kit, the EnSite System is intended to display the position of conventional electrophysiology catheters in the heart.

Technological Characteristics:

The new device has the same technological characteristics as the legally marketed predicate device

Non-clinical Performance Data:

The changes made to the EnSite System underwent a battery of bench and user tests. Device validation testing was conducted in accordance with in-house procedures.

Conclusion:

An evaluation of the device changes indicates that the device is as safe and effective as the previously marketed device to which it is being compared and does not raise any new issues of safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

St. Jude Medical
c/o Ms. Karen J. McKelvey
Regulatory Affairs Manager II
1350 Energy Lane, Suite 110
St. Paul, MN 55108

Re: K083328
Trade/Device Name: EnSite System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Dated: April 22, 2009
Received: April 23, 2009

Dear Ms. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083328

9. Indications for Use

Device Name: EnSite System

Indications for Use:

The EnSite System is indicated for patients for whom electrophysiology studies are indicated.

- When used with the EnSite Catheter, the EnSite System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

OR

- When used with the EnSite NavX Surface Electrode Kit, the EnSite System is intended to display the position of conventional electrophysiology catheters in the heart.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083328